

### **REMARKS**

The Office Action mailed June 5, 2003 has been received and carefully considered. Upon entry of the present amendment, claims 1, 2, 5, 7-40, and 42-47 will be pending. Currently, claims 13-40, and 42-43 are withdrawn and claims 1-12 stand rejected. Claims 1-12 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the invention. Claims 1-9 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over USSR Inventor's certificate 1697756 to Gorbachevskiy et al. (Gorbachevskiy) as referenced by U.S. Pat. No. 5,798,096 to Pavlyk (Pavlyk). Claims 1-12 stand rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over WO 01/49336 to Lopatine et al. (Lopatine). Applicants respectfully traverse these rejections.

#### **I. Information Disclosure Statement**

Applicants thank the Examiner for returning a copy of the Form PTO-1449 submitted by Applicants along with an Information Disclosure Statement on April 11, 2002. Applicants note, however, that the Examiner appears to have inadvertently neglected to initial the references and sign the Form PTO-1449 before returning a copy to Applicants per MPEP 609. Applicants respectfully request that the Examiner re-send a copy of the Form PTO-1449 with the Examiner's initials indicating that the references have been considered or advise Applicants why the Examiner did not consider the cited references.

Applicants also note that a Supplemental Information Disclosure Statement along with the requisite fee is submitted herewith. Applicants respectfully request that the Examiner also consider these references and return a copy of the Form PTO-1449 with the Examiner's initials in the left hand column indicating that the Examiner has considered the references per MPEP 609.

## **II. Amendments to Claims and Grouping of Claims**

Claims 1, 2, 5, 7-10 and 12 are amended.

Claims 3, 4, 6 and 41 are cancelled without prejudice.

New claims 44-47 are presented for examination, all of which are dependent from claim 1. Support for new claims 44-47 can be found at least at page 14, lines 4-30. Additional support for the new claims and claim amendments can be found throughout the specification and claims as originally filed; the new claims do not introduce new matter into the Application.

Accordingly, Applicants respectfully request that claims 44-47 be included in Group I and be examined together with claims 1-12.

## **III. Rejection under 35 U.S.C. § 112**

Claims 1-12 stand rejected under 35 U.S.C. § 112, second paragraph. In particular the Examiner has asserted:

(a) that claims 1-3 are indefinite, omnibus-type claims which fail to positively set forth the composition of the hydrogel because the recitation of less than 3.5% includes 0%. Office Action at 3. Applicants respectfully submit that claim 1 prior to its amendment herein was definite because persons skilled in the art would readily understand that a hydrogel comprising polyacrylamide, in the amount of less than 3.5%, must contain some amount of the polyacrylamide. Such an amount is greater than 0%. Nonetheless, in the interest of expediting prosecution, and without acquiescing in the Examiner's reasoning, Applicants amended claim 1 to recite a lower limit. The amended claim continues to be definite and this rejection should be withdrawn. Applicants reserve the right to pursue claims of the same or similar scope as claim 1 (prior to its amendment herein) in any other applications.

(b) that claim 1 is indefinite for failing to positively claim the composition of the hydrogel due to the use of the term "obtainable." Office Action at 3. Claim 1 as amended does

not include the term "obtainable." Applicants respectfully submit that claim 1 as amended obviates the Examiner's rejection on this ground and that this rejection should therefore be withdrawn.

(c) that claims 2-4 are unclear, i.e., "what parameters the 95% encompasses." Office Action at 3. Applicants respectfully submit that the amendments to the claims obviate the Examiner's rejection and that this rejection should therefore be withdrawn.

(d) that claims 6 and 7 which use the phrase "complex viscosity" are indefinite. Office Action at 3. Applicants respectfully submit that the phrase "complex viscosity" is one which has meaning to those of skill in the art and which is used to describe the viscosity of a homogenized polymer, such as a hydrogel.

(e) that the wording of claim 10 is "confusing." Office Action at 3. Applicants respectfully submit that claim 10 as amended obviates the Examiner's rejection, which should therefore be withdrawn.

(f) that claim 12 is indefinite for defining a hydrogel while attempting to further define an endoprosthesis. Office Action at 3. Applicants respectfully submit that claim 12 as amended obviates the Examiner's rejection, which should therefore be withdrawn.

#### **IV. Rejection under 35 U.S.C. § 102(b)/103(a)**

Claims 1-9 are rejected as anticipated under 35 U.S.C. § 102(b) or in the alternative under 35 U.S.C. § 103(a) as obvious over Gorbachevskiy as referenced by Pavlyk. Office Action at 4. Applicants respectfully traverse this rejection.

A translated "Description of Invention pertaining to Inventor's Certificate" of Gorbachevskiy is included in the Information Disclosure Statement submitted herewith by Applicants.

It is well established that to anticipate a claimed invention under § 102 of the Patent Code, a reference must disclose each and every element of the claimed invention either expressly or inherently. *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997). Furthermore, it is also well established that the reference must be enabling. *In re Epstein*, 31 USPQ2d 1817 (Fed. Cir. 1994).

A proper obviousness analysis under § 103(a) requires consideration of: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success.” *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). In addition, the prior art reference(s) must teach or suggest all of the claim limitations. The teaching or suggestion to combine and the reasonable expectation of success must both be found in the prior art, and not in Applicants’ disclosure. *Id* at 493. *See also* MPEP 2142.

Neither Gorbachevskiy as summarized in Pavlyk nor the Description of Invention of Gorbachevskiy teach, disclose, or suggest a hydrogel suitable for use as an endoprosthesis, the hydrogel comprising polyacrylamide which is a polymer of acrylamide cross-linked with methylene bis-acrylamide, wherein the acrylamide and methylene bis-acrylamide are combined in a molar ratio of 150:1 to 1000:1 and wherein the hydrogel includes about 0.5 to 3.5% polyacrylamide by weight, based on the total weight of the hydrogel. Applicants’ claimed hydrogel further comprises water or an aqueous solution, has a content of acrylamide and methylene bis-acrylamide monomers below 50 ppm and has an elasticity module from about 10 to 700 Pa and a complex viscosity from about 2 to 90 Pas.

At most, Gorbachevskiy teaches a hydrogel comprising 3% by weight of a polymer based on acrylamide. Gorbachevskiy does not teach the ratios of methylene bis-acrylamide as a cross-linker with respect to acrylamide or the complex viscosity or elasticity modulus of the hydrogel, much less that such a hydrogel would be suitable for use as an endoprosthesis. In fact, Pavlyk discloses that the hydrogel of Gorbachevskiy and all other hydrogels having less than 3.5% by

weight of a cross-linked polyacrylamide are unstable and suitable for use only as a base of medical ointments or electro-conducting immersion media. Pavlyk Col. 3, lines 45-47.

Conversely, Applicants' claimed invention is suitable for use as an endoprosthesis and, despite the overlapping weight content, has physical properties which are not disclosed by Gorbachevskiy. These properties could not be inherent based on the instability of Gorbachevskiy's invention. Even if Gorbachevskiy's hydrogel were stable, it does not necessarily follow that all hydrogels having 3% by weight of a cross-linked polymer have the same compositions and the same physical properties. For example, one of ordinary skill in the art will appreciate that medical ointments and immersion media for electro-conducting would not have an elasticity as high as that of Applicants' claimed invention.

Furthermore, based on the teachings of Pavlyk - which describes hydrogels having less than 3.5% by weight of a cross-linked polyacrylamide as unstable - one of ordinary skill in the art would certainly not be motivated to make a gel suitable for endoprosthesis which corresponds to Applicants' claimed invention. Pavlyk states that hydrogels containing less than 3.5% by weight of cross-linked polyacrylamide can only be used as a base for medicinal ointments or electro-conducting immersion media. Thus, based on Pavlyk's teaching, Gorbachevskiy fails to disclose (or suggest) a stable hydrogel comprising a cross-linked polyacrylamide. Gorbachevskiy is therefore not enabling prior art with respect to Applicants' invention. That invention is a hydrogel including less than about 3.5% by weight of a polyacrylamide comprising acrylamide cross-linked with methylene bis-acrylamide. For at least this reason, Gorbachevskiy is not a valid prior art reference, and it must be withdrawn as a basis for the rejections.

Even if, *arguendo*, Gorbachevskiy could be properly used as prior art, it would not have disclosed or suggested Applicants' invention. For example, Gorbachevskiy fails to disclose the Applicants' claimed monomer content, or claimed properties of the hydrogel.

Gorbachevskiy would have failed to suggest to a person of ordinary skill in the art Applicants' claimed invention because it lacks any suggestion to modify his hydrogel so as to obtain Applicants' claimed invention, as discussed above. Such a modification could only have

been made with the benefit of hindsight provided by Applicants' invention, which is not permissible in the non-obviousness analysis.

Accordingly, as Gorbachevskiy does not teach, disclose, or suggest each and every element of the claimed invention, nor would one of ordinary skill in the art be motivated to modify Gorbachevskiy to arrive at the claimed invention, Applicants respectfully submit that the rejection must be withdrawn.

#### **V. Rejection under 35 U.S.C. § 102(e)/103(a)**

Claims 1-12 are rejected as anticipated under 35 U.S.C. § 102(e) or in the alternative under 35 U.S.C. § 103(a) as obvious over Lopatine. Office Action at 5. Applicants respectfully traverse this rejection because Lopatine is not prior art under provisions of 35 U.S.C. § 102(e) with respect to Applicants' Application. The Application claims priority from a U.S. provisional application 60/228,081, filed on August 25, 2000. The revised Section 102(e) is applicable to a PCT application filed on or after November 29, 2000. This Section provides that such a PCT application designating the U.S. and published in English is Section 102(e) prior art as of its PCT filing date. Lopatine is an International Application filed on December 29, 1999, prior to November 29, 2000. Since the provisions of the revised Section § 102(e) do not apply to International Applications filed prior to November 29, 2000, Lopatine is not prior art to this application under Section § 102(e). *See* MPEP 706.02(f)(1). For at least this reason, withdrawal of all rejections over Lopatine is respectfully requested.

#### **Conclusion**

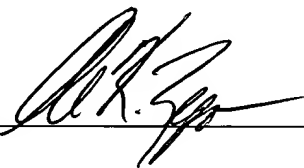
For at least the reasons stated above, claims 1-12 and 44-47 are in condition for allowance. Accordingly, Applicants respectfully request that the amendments be entered and the Application be allowed and passed to issue.

In re U.S. Patent Application of Jens PETERSEN et al.  
Serial No.: 09/938,670 Filing Date: August 27, 2001  
Title: POLYACRYLAMIDE HYDROGEL AND ITS USE AS AN ENDOPROSTHESIS  
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In the event any outstanding issues remain, Applicants would appreciate the courtesy of a telephone call to Applicants' undersigned representative to resolve such issues in an expeditious manner.

Date: November 5, 2003

Respectfully submitted,

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